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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,959	09/12/2001	Paul H. Weigel	3554.049	6465

7590 06/24/2004

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EXAMINER
WAX, ROBERT A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,959	WEIGEL ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14,39-41 and 60-312* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14,39-41 and 60-312* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11142003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed November 13, 2003 has been considered. Please see the attached initialed PTO-1449. References 1, 6, 12, 14 and 18-27 were lined through because they did not discuss hyaluronic acid and seemed to have been cited by mistake. References K-O were lined through because Examiner does not read Japanese.

Drawings

2. The drawing of Figure 14 was received on September 12, 2001. This drawing is acceptable.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 39-41, 60-63, 67-81, 90-98, 117-119, 126-133, 150-163, 192-224, 247-257 and 280-290 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant methods of producing hyaluronic

acid wherein the DNA encoding the hyaluronate synthase is from Streptococcus equisimilis or Streptococcus pyogenes, does not reasonably provide enablement for recombinant methods of producing hyaluronic acid wherein the DNA encoding the hyaluronate synthase is from other sources, including Group A HAS and Group C HAS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claims read on Bacillus host cells comprising DNA encoding enzymatically active hyaluronan synthase, recombinant methods of producing hyaluronic acid and hyaluronic acid produced by those processes wherein the DNA encoding the hyaluronate synthase is from any organism whatsoever, or Group A organisms or Group C organisms. These latter are informal names given to groups of organisms that produce Group A or Group C hyaluronan synthase, respectively. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to Bacillus host cells comprising DNA encoding enzymatically active hyaluronan synthase, recombinant methods of producing hyaluronic acid and hyaluronic acid produced by those processes wherein the DNA encoding the hyaluronate synthase is from any organism whatsoever, or Group A organisms or Group C organisms.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is very large because of the large number of organisms that produce hyaluronic acid (almost all organisms on the planet); (2) the amount of guidance provided by the specification is limited since only the isolation of the gene from *S. equisimilis* is shown. More guidance is needed in view of the evidence in the specification that the DNA encoding seHAS and that encoding spHAS do not cross-hybridize. This shows that one of skill in the art would not expect to be able to use the disclosed DNA as a probe to isolate DNA encoding

other hyaluronate synthases from other organisms. Additionally, there is no guidance as to what might constitute an organism that makes Group A or Group C hyaluronan synthase. Continuing, (3) the specification shows how the DNA encoding seHAS was obtained; (4) the nature of the invention is the placement of DNA encoding hyaluronate synthase into a host cell to force manufacture of hyaluronic acid. The prior art (5) shows that hyaluronic acid is well known, that membranes comprising hyaluronate synthase have been used to prepare hyaluronic acid and that Applicants are apparently the first to isolate the DNA encoding seHAS; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low since, with no useful probe, finding a needle in a haystack would be much easier than finding the DNA encoding the desired enzyme. Finally, (8) the claims are enormously broad because any DNA encoding any hyaluronate synthase is encompassed by the claims.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

5. Claims 11, 39-41, 60-63, 67-81, 90-98, 117-119, 126-133, 150-163, 192-224, 247-257 and 280-290 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are

directed to Bacillus host cells comprising DNA encoding enzymatically active hyaluronan synthase, recombinant methods of producing hyaluronic acid and hyaluronic acid produced by those processes wherein the DNA encoding the hyaluronate synthase is from any organism whatsoever, or Group A organisms or Group C organisms and is defined only by one functional characteristic (i.e., the DNA encodes hyaluronate synthase). The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the DNA used in the claimed process only by one of its functional properties. The court held this sort of functional definition insufficient. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes

that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *UC v. Lilly*, at *24-*25, thus, the above claims lack adequate written description.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 150-191 and 280-312 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Meyer et al.

Meyer et al. teach hyaluronic acid. This teaching clearly anticipates the above claims. Applicant has made no showing as to what the differences might be between the claimed hyaluronic acid and that taught by Meyer et al.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 11, 39-41, 60-63, 67-77, 192-213 and 236-246 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,455,304. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is a variation of the invention of the patented claims to *S. pyogenes* nucleic acid, vector and *Bacillus subtilis* host cells; such claims would not have been restricted, had they appeared in the same application.

10. Claims 11-14, 39-41, 62-66, 69-149 and 192-279 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 60-67 and 69-73 of copending allowed Application No. 09/469,200. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the instantly claimed method of making hyaluronic acid is a variation of the invention of the allowed claims to *S. equisimilis* nucleic acid, vector and host cells; such claims would not have been restricted, had they appeared in the same application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 11, 39-41, 60-63, 67-77, 192-213 and 236-246 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 43-61 of copending Application No. 10/117,795. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is more general than the method of making hyaluronic acid in the other application, which is limited to nucleic acid from *S. pyogenes*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 11, 39-41, 60-63, 67-77, 192-213 and 236-246 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 60-64 of copending Application No. 10/011,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is a

variation of the invention of the other claims to nucleic acid encoding at least *S. pyogenes* hyaluronate synthase; such claims would not have been restricted, had they appeared in the same application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 11-14, 39-41 and 60-312 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 60-72 of copending Application No. 10/011,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is a variation of the invention of the other application's claims to nucleic acid, vector and *Bacillus subtilis* host cells; such claims would not have been restricted, had they appeared in the same application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 11, 39-41, 60-63, 67-77, 192-213 and 236-246 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 and 35-42 of copending Application No. 10/124,222. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is a variation of the invention of the other application's claims to *S. pyogenes* nucleic acid,

and method of making hyaluronic acid; such claims would not have been restricted, had they appeared in the same application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 11, 39-41, 60-63, 67-77, 192-213 and 236-246 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-309 of copending Application No. 10/172,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of making hyaluronic acid is a variation of the invention of the other application's claims to nucleic acid, vector and *Bacillus subtilis* host cells; such claims would not have been restricted, had they appeared in the same application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

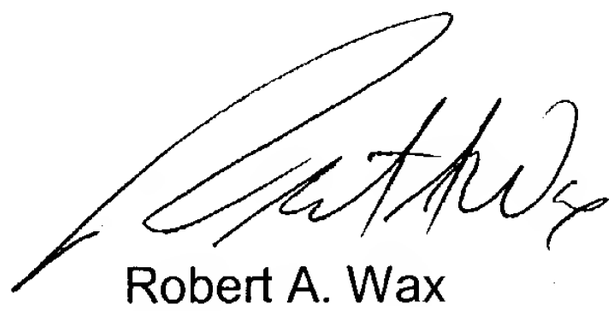
16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-

0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653